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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,414	11/22/2000	Hiroaki Suga	11520.0222	2737

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/721,414	Applicant(s) SUGA ET AL.	
	Examiner J. Douglas Schultz	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Applicants' attention is directed to the claim numbering, where claim 3 is listed twice. For the purposes of this restriction, said claims are temporarily re-designated as claims 4 and 3B, dependent upon their order of appearance in the claim set. However, correction is required in applicant's next response.

Applicants' attention is further drawn to claims 1, 5 and 7. Claim 1 recites SEQ ID NO: 7 twice. In claims 5 and 7, applicants are directed to the recitation of nucleotides pertaining to SEQ ID NO: 9. It appears that "nucleotides 89" recited therein may have been intended to read as "nucleotides 1-89". If this is applicants' intention, correction is required.

The following restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-XI. Claims 1 and 2, drawn respectively to a nucleic acid molecule comprising a polynucleotide having a sequence of SEQ ID NOS:5-15, and complementary sequences thereof, classified for example in class 536, subclass 23.1.

XII-XXII. Claim 3, drawn respectively to a nucleic acid molecule comprising a polynucleotide from an RNA having a sequence of nucleotides 1-85 of SEQ ID NO:5, nucleotides 1-89 of SEQ ID NO:6, nucleotides 1-89 of SEQ ID NO:7,

nucleotides 1-88 of SEQ ID NO:8, nucleotides 1-89 of SEQ ID NO:9, nucleotides 1-88 of SEQ ID NO:10, nucleotides 1-88 of SEQ ID NO:11, nucleotides 1-88 of SEQ ID NO:12, nucleotides 1-88 of SEQ ID NO:13, nucleotides 1-89 of SEQ ID NO:14, nucleotide 1-88 of SEQ ID NO:15, and complementary sequences thereof, classified for example in class 536, subclass 23.1..

XXIII-XXXVI. Claims 4 and 5, drawn respectively to a nucleic acid molecule comprising the polynucleotide selected from the group consisting of an RNA having a sequence of nucleotides 86-146 of SEQ ID NO:5, nucleotides 90-151 of SEQ ID NO:6, nucleotides 90-150 of SEQ ID NO:7, nucleotides 89-150 of SEQ ID NO:8, nucleotides 90-150 of SEQ ID NO:9, nucleotides 89-149 of SEQ ID NO:10, nucleotides 89-149 of SEQ ID NO:11, nucleotides 89-149 of SEQ ID NO:12, nucleotides 89-149 of SEQ ID NO:13, nucleotides 90-150 of SEQ ID NO:14, nucleotides 89-148 of SEQ ID NO:15, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, and complementary sequences thereof, classified for example in class 536, subclass 23.1.

XXXVII-XLVII. Claim 6, drawn respectively to methods for constructing cis-aminoacylating catalytic RNA molecules comprising the steps of providing tRNA-like molecules and attaching a ribozyme sequence to the 5' end of the tRNA like molecule, said ribozyme sequence being selected from the group consisting of nucleotides 1-85 of SEQ ID NO:5, nucleotides 1-89 of SEQ ID

NO:6, nucleotides 1-89 of SEQ ID NO:7, nucleotides 1-88 of SEQ ID NO:8, nucleotides 89 of SEQ ID NO:9, nucleotides 1-88 of SEQ ID NO:10, nucleotides 1-88 of SEQ ID NO:11, nucleotides 1-88 of SEQ ID NO:12, nucleotides 1-88 of SEQ ID NO:13, nucleotides 1-89 of SEQ ID NO:14 and nucleotide 1-88 of SEQ ID NO:15., classified for example in class 435, subclass 6.

LXVIII-LXI. Claims 7, 8, and 11, drawn respectively to a method of identifying cis-aminoacylating catalytic RNA molecules comprising the steps of attaching a ribozyme domain molecule to a tRNA-like molecule to obtain a pool of ribozyme-tRNA molecules and screening said pool for those molecules with cis-aminoacylating catalytic activity, wherein the tRNA-like molecule optionally has a sequence selected from the group consisting of nucleotides 86-146 of SEQ ID NO:5, nucleotides 90-151 of SEQ ID NO:6, nucleotides 90-150 of SEQ ID NO:7, nucleotides 89-150 of SEQ ID NO:8, nucleotides 90-150 of SEQ ID NO:9, nucleotides 89-149 of SEQ ID NO:10, nucleotides 89-149 of SEQ ID NO:11, nucleotides 89-149 of SEQ ID NO:12, nucleotides 89-149 of SEQ ID NO:13, nucleotides 90-150 of SEQ ID NO:14, nucleotides 89-148 of SEQ ID NO:15, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, classified for example in class 435, subclass 6.

LXII-LXXII. Claims 7, 8, and 11, drawn respectively to a method of identifying cis-aminoacylating catalytic RNA molecules comprising the steps of attaching a

ribozyme domain molecule to a tRNA-like molecule to obtain a pool of ribozyme-tRNA molecules and screening said pool for those molecules with cis-aminoacylating catalytic activity, wherein the tRNA-like molecule has a sequence selected from the group consisting of nucleotides 1-85 of SEQ ID NO:5, nucleotides 1-89 of SEQ ID NO:6, nucleotides 1-89 of SEQ ID NO:7, nucleotides 1-88 of SEQ ID NO:8, nucleotides 89 of SEQ ID NO:9, nucleotides 1-88 of SEQ ID NO:10, nucleotides 1-88 of SEQ ID NO:11, nucleotides 1-88 of SEQ ID NO:12, nucleotides 1-88 of SEQ ID NO:13, nucleotides 1-89 of SEQ ID NO:14 and nucleotide 1-88 of SEQ ID NO:15., classified for example in class 435, subclass 6.

LXXIII-LXXXIII. Claims 10 and 12, drawn respectively to a method of obtaining a trans-aminoacylating catalytic RNA molecule comprising providing an RNA molecule having a sequence selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14 and SEQ ID NO:15, and cleaving the RNA molecule with RNase P to obtain the trans-aminoacylating catalytic RNA molecule and an aminoacyl acceptor domain, classified for example in class 435, subclass 6.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, each group of the group set I-XI recites an individual sequence. Each sequence, and thus each group, is considered to be unrelated to other members of its group set, and is subject to restriction. Similarly, each group within each respective group set of XII-XXII, XXIII-XXXVI, XXXVII-XLVII, LXVIII-LXI, LXII-LXXII, and LXXIII-LXXXIII are considered to be unrelated to the other member of its group set because each recites a different sequence from the others in its group set, and are also subject to restriction. The reasoning for why each sequence is considered distinct is given in the next paragraph. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. See MPEP 803.04 and 2434.

Each sequence listed in the claims is considered to comprise one invention, and each individual sequence has accordingly been placed into a separate group for the reasons given herein below. These sequences can be generally divided into three classes: a) the full length sequences of SEQ ID NOS: 5-15 and 20-22, b) a 5'- region of SEQ ID NOS: 5-15 corresponding to approximately to nucleotides 1-85 of each SEQ ID NO: listed above, and c) a 3'- region of SEQ ID NOS: 5-15 corresponding to approximately to nucleotides 86-150 of each SEQ ID NO: listed above. Although all such sequences claimed are each ribozymes or regions thereof, such sequences are considered to be unrelated, since each sequence or region of each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence, and each sequence comprises distinct functional characteristics, described for example at page 8 of the specification, wherein the region

corresponding to nucleotides 1-85 of any of SEQ ID NOS: 5-15 are disclosed as 5'- leader domains. Such 5'- regions are distinct not only from each other, but also from both the 3'- region and from the larger sequence of which each is a part. Because each sequence is considered structurally and functionally unique, each sequence is considered distinct. Furthermore, a search of more than one such sequence claimed in the above listed claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence or region of such a sequence is considered to be a reasonable number of sequences for examination. Accordingly, should applicants desire to elect an invention comprising a sequence or region as outlined above, applicants are required to elect the group that corresponds to one (1) sequence or region of said sequence from the above identified groups.

Furthermore, all groups in group set I-XXXVI, all of which claim distinct nucleotide sequences, are subject to restriction for the reasons given above. All groups of group set LXVIII-LXXII, which are drawn to methods of identifying cis-aminoacylating catalytic RNA molecules, are also subject to restriction as described above because each utilizes distinct nucleotide sequences.

The product of groups I-XXXVI is considered to be related to the groups of group set XXXVII-XLVII, which claim methods of constructing cis-aminoacylating RNA molecules, as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the instant method steps of constructing such

catalytic RNA molecules can be used to ligate any RNA sequence to any other RNA sequence, such sequences being wholly unrelated to the instantly claimed ligation process of joining a tRNA to a ribozyme. For example, one can use the instant method to ligate a primer amplicon onto a sequence to be amplified.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is proper because these methods appear to constitute patentably distinct inventions for the following reasons. Groups XXXVII-XLVII are distinct from all other groups, because these groups are directed to methods of constructing cis-aminoacylating catalytic RNA molecules, which require attaching a 5'-end of a ribozyme sequence to a tRNA molecule, which is not required of any other groups.

The groups of group set LXVIII-LXXII are distinct from all other groups, because these groups are drawn to methods of screening for cis-aminoacylating catalytic RNA molecules, which requires screening a pool of nucleotides for the presence of ribozymes that have been aminoacyl-modified, which is not required of any other groups.

The groups of group set LXXIII-LXXXIII are distinct from all other groups, because groups LXXIII-LXXXIII are drawn to methods of screening for trans-aminoacylating catalytic RNA molecules, which requires cleaving RNA sequences with RNase P and then screening a large pool of molecules that may or may not be nucleotides for the presence of such molecules that have been aminoacyl-modified, the steps of which are not required of any other groups. Because the steps required in these methods are not required of any other groups as outlined above, they would thus be materially different. Furthermore, a search and examination of all

these methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, and the subject matter and steps are divergent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER